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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,474	09/25/2003	Douglas McNeel	011335.52703US	4831

23911 7590 08/19/2005

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,474	MCNEEL, DOUGLAS	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,23-25 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,23-25 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 6/13/2005 is acknowledged. Claims 1-9,23-25,28-30, and 32 are pending in the instant application. Applicant amended claim 1 and 32. It is noted that claim 32 has been amended to depend on withdrawn claim 26, therefore claim 32 is now withdrawn as well.

Claims 1-9,23-25,28-30 are currently under consideration.

The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

The rejection of claims 1-7, 8, 9, 23-24, 28, 30, 32 under 35 U.S.C. 102(e) as being anticipated by US Patent 6,328,969 (Dec. 11, 2001), hereafter referred to as Houghton et al, is withdrawn.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9, 23-25, 28-30, and 32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing a T cell or B cell mediated immune response to PAP in a mammal, comprising intramuscular, intravascular, intravenous, or intra-arterial administration of a recombinant pTVG or vaccinia virus construct comprising a polynucleotide sequence a PAP sequence linked to a promoter, does not reasonably provide enablement for a method for inducing any immune response to PAP in a mammal to treat prostate cancer, comprising any route of administration of any recombinant DNA construct comprising a polynucleotide sequence a PAP sequence linked to a any transcriptional regulatory

element. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments and amendments to the claims filed 6/13/2005 have been fully considered but they are not fully persuasive. Applicant's arguments would most likely be found fully persuasive in overcoming this rejection if the data supplied as Exhibit I and discussed in the response (paragraph 1, pg 12) was provided in the form of a declaration under 37 C.F.R. § 1.132. Until then the treatment is not enabled for reasons of record.

Double Patenting

The objection of claim 30 under 37 CFR 1.75 as being a substantial duplicate of claim 32, is withdrawn in view of applicant's amendments to claim 32. Since claim 32 now depends on previously withdrawn claim 26 it is now withdrawn from further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5- 9, 23-24, 28, 30, are newly rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6/328,969 (July 20, 1999), hereafter referred to as Spitler et al.

Spitler et al. provides guidance on a method for preventing and treating prostate cancer in a human with a vaccine encoding human prostate antigens (Col. 1, lines 10-15). Wherein, an anti-tumor immune response is induced in an actual or potential prostate tumor-bearing subject; with an expression system capable of generating in situ said antigen (Col. 2, lines 50-60). Wherein, said antigen may be prostatic acid phosphatase (PAP) (Col. 3, line 64-Col.4, line 11; Col. 4, line 62-Col.5, line 5). Further, Spitler et al. teaches that the prostate is not an essential organ and that the vaccine can induce elimination of the prostate organ without adversely impacting the health of the subject (Col. 2 lines 35-45). Said vaccine induced elimination inherently includes autoimmune prostatitis. Spitler et al. teaches that the expression system used as vaccine includes DNA encoding PAP, or portions of these administered in a viral expression vector, such as vaccinia or pox virus, or bacterial vectors such as BCG, or Naked DNA (Col. 3, lines 35-60; Col. 8, lines 1-15). Such expression vectors inherently include transcription regulatory elements. Further, wherein the effect of the cancer is to enhance the potential of the immune system, generating T cell responses as well as the production of antibodies (Col. 8, lines 20-25). Spitler et al. teaches that the vaccine may be administered intracutaneously, subcutaneously, intramuscularly, intravenously, or by oral administration in a pharmaceutical formulation, such as Hank's solution or Ringer's solution (Col. 2, lines 55-58; Col. 8, lines 41-44). Thus, by teaching all the limitations of the claims as written, Spitler et al. anticipates the instant invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 25, and 29 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6/328,969 (July 20, 1999), hereafter referred to as Spitler et al.

Spitler et al. provides guidance on a method for preventing and treating prostate cancer in a human with a vaccine encoding human prostate antigens (Col. 1, lines 10-15). Wherein, an anti-tumor immune response is induced in an actual or potential prostate tumor-bearing subject; with an expression system capable of generating in situ said antigen (Col. 2, lines 50-60). Wherein, said antigen may be prostatic acid phosphatase (PAP) (Col. 3, line 64-Col.4, line 11; Col. 4, line 62-Col.5, line 5). Further, Spitler et al. teaches that the prostate is not an essential organ and that the vaccine can induce elimination of the prostate organ without adversely impacting the health of the subject (Col. 2 lines 35-45). Said vaccine induced elimination inherently includes autoimmune prostatitis. Spitler et al. teaches that the expression system used as vaccine includes DNA encoding PAP, or portions of these administered in a viral expression vector, such as vaccinia or pox virus, or bacterial vectors such as BCG, or Naked DNA (Col. 3, lines 35-60; Col. 8, lines 1-15). Such expression vectors inherently include transcription regulatory elements. Further, wherein the effect of the cancer is to enhance the potential of the immune system, generating T cell responses as well as the production of antibodies (Col. 8, lines 20-25). Spitler et al. teaches that the vaccine may be administered intracutaneously,

subcutaneously, intramuscularly, intravenously, or by oral administration in a pharmaceutical formulation, such as Hank's solution or Ringer's solution (Col. 2, lines 55-58; Col. 8, lines 41-44). Finally, Spitler et al. teaches that the vaccine may be used as a pharmaceutical or veterinary vaccine (Col. 2, lines 55-58). Spitler et al. does not teach that the polynucleotide sequence encodes a rodent PAP, that the polynucleotide sequence encoded PAP is comprised within a plasmid vector with a backbone of pNGVL3 containing an ISS motif, or that the polynucleotide sequence encoded PAP is comprised within a pTVG4 plasmid vector.

Based on the guidance provided by Spitler et al. on a method of administering a pharmaceutical or veterinary vaccine comprising a PAP polynucleotide using any expression vector, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Spitler et al. by administering a vector comprising an animal specific PAP, such as a rodent PAP to treat prostate cancer in a rodent, such as a rat. Further, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Spitler et al. by using any vector including a plasmid vector with a backbone of pNGVL3 containing an ISS motif, or a pTVG4 plasmid vector to administer the polynucleotide sequence encoded PAP.

A practitioner in the art would be motivated to modify the method of Spitler et al. by using a rodent PAP to treat prostate cancer in rodents in order to insure that a species specific immune response was induced. Further, a practitioner in the art would be motivated to modify the method of Spitler et al. by administering the polynucleotide sequence encoded PAP in different vectors in order to optimize the efficacy of the vaccine.

The person of ordinary skill in the art would have a reasonable expectation of success because using a polynucleotide sequence encoding a rodent PAP, instead of a human PAP would have been a minor and routine modification that was well known in the art at the time of invention. Likewise, the use of different vectors to express the polynucleotide sequences *in situ* was routine in the art at the time of invention.

No Claims Allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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